AUG 8 2000



**510 (k) Summary** K002225

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

## I. General Information.

**Establishment:**

- Address: Siemens Medical Systems, Inc.
  186 Wood Avenue South
  Iselin, N.J. 08830

**Registration Number:** 2240869

**Contact Person:** Mr. Jamie Yieh
Technical Specialist, Regulatory Submissions
(732) 321-4625
(732) 321-4841

**Date of Summary Preparation:** 6/28/00

**Device Name:**

•Trade Name: OR Table with the MAGNETOM OPEN Viva

•Classification Name:
Magnetic Resonance Diagnostic Device, CFR § 892.1000

•Classification: Class II

•Performance Standards:
None established under Section 514 the Food, Drug, and Cosmetic Act.

## II. Safety and Effectiveness Information Supporting Substantial Equivalence.

**• Device Description:**

**•Intended Use**
The MAGNETOM OPEN viva with the OR Table is an open, whole body scanner. The MAGNETOM Open Viva with the OR Table is indicated for use as diagnostic imaging device to produce transversal, sagittal, coronal and oblique images of the internal structures of the head or body. The images produced by the MAGNETOM OPEN viva with the OR Table reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis. The OR Table with the optional Interactive MR Localizer (IMRL) will be an option for intra-operative and interventional procedures.

**• Technological Characteristics**
The MAGNETOM OPEN Viva with the new OR Table is substantially equivalent to the MAGNETOM OPEN Viva System.

**• General Safety and Effectiveness Concerns:**
The introduction of the new OR Table has no significant effect on the following MR safety and performance parameters:

[Safety]
- Maximum Static Field
- Rate of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Level

[Performance]
- Specification Volume
- Signal to Noise
- Image Uniformity
- Geometric Distortion
- Slice Profile, Thickness and Gap
- High Contrast Spatial Resolution

Since we are simply adding an optional OR Table to the already existing MAGNETOM OPEN Viva system, which will have exactly the same components (i.e. 0.2 Tesla Magnet, 15mT gradients, RF, and software application), the optional OR Table will not have any significant effect on the currently available system. The OR Table will be used in various applications ranging from regular diagnostic scans to interventional/intra-operative procedures with the optional MR Localizer and In Room (MR

Guided) Console. To ensure that the OR Table or other MR accessories does not influence the Magnetom Open Viva, Siemens did an evaluation on possible interference from the OR table which could affect the safety or effectiveness with the currently available systems. The evaluations showed that the Magnetom Open Viva System was not effected in the parameters stated above by the new OR Table.

• **Substantial Equivalence:**
Laboratory testing were performed to support this claim of substantial equivalence and to show that the technological differences do not raise any new questions pertaining to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 8 2000

Siemens Medical Systems, Inc.
c/o Reiner Krumme
TUV Rheinland of North America
12 Commerce Road
Newton, CT 06470

Re: K002225
OR Table for the MAGNETOM Open VIVA System
Dated: July 20, 2000
Received: July 24, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Krumme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

**510(k) Number (if known)** K002225

**Device Name:** OR Table for the MAGNETOM OPEN VIVA System

**Indications for Use:**

The MAGNETOM OPEN viva with the OR Table is an open, whole body scanner. The MAGNETOM Open Viva with the OR Table is indicated for use as diagnostic imaging device to produce transversal, sagittal, coronal and oblique images of the internal structures of the head or body. The images produced by the MAGNETOM OPEN viva with the OR Table reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis. The OR Table with the optional Interactive MR Localizer (IMRL) will be an option for intra-operative and interventional procedures.

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Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use ____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002225